



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/182,645	10/30/1998	JIA-HE LI	23737	2236

29700 7590 08/07/2002
GUILFORD PHARMACEUTICALS, INC.
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/07/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/182,645

Applicant(s)

LI ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,28-31,35-38 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-25,28-31 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1617

DETAILED ACTION

Receipt of the appeal briefing submitted May 10, 2002 is acknowledged. In reconsideration, the finality of the office action mailed December 3, 2001 is withdrawn in favor of the following office action.

1. Claims 1-25, 28-31, 35-39 and 46-49 are pending in the application. Claims 1-25, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 28-31 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 submitted on Feb. 1, 2000.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 46-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing the particular PARG inhibitors as disclosed in the specification, e.g., pages 35-41, does not reasonably provide enablement for "PARG inhibitor" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant uses functional limitation 'inhibitor of poly(ADP-ribose)glycohydrolase (PARG inhibitor)' to define the agents employed in the method, without providing guidance, direction with respect to the structural features required to be a PARG

Art Unit: 1617

inhibitor, and leave the search of PARG inhibitors other than those expressly disclosed herein a pure fishing expedition. A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those 'inhibitor of poly(ADP-ribose)glycohydrolase' within claimed scope. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: the vice of a functional claim exists not only when a claim is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first or second paragraph. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted *General Electric Company v. Wabash Appliance Corporation et supra*, at 468.

Claim Rejection 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1617

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (CH 1077644A, Abstract, DERWENT ACC-NO: 1997-065937, of record, and English translation provided by applicants), Ning (CH 1113711, Abstract from DERWENT-ACC-NO: 1997-416112, of record and the English Translation provided by Applicants) and Tanuma (AB and AC).

5. Wang teaches method of treatment of diabetes comprising administering ginseng in the form of tea to the patient. See the abstract. A tea bag containing 1.8 gram of ginseng powders and extract. See page 3, the application example of the English translation. Ning teaches method of treatment of ischemia comprising administering ginseng in the form of tea to the patient. See the abstract. A tea bag weigh about 15 g, which contains about 1% of ginseng extract. See, page 2, the last paragraph bridging to page 3, the third paragraph of the English translation. The ginseng is administered in the form of tea. See both abstracts. Tanuma teach that ginseng hot water extract containing the lignin glycoside herein. See page 5, lines 2-4, the embodiment 1 at page 5, and page 12 in JP 3-205402 the translated copy. Therefore the claimed method herein read on the method taught by Wang and Ning. Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Claim 49 is properly rejected because it is well known in the art that reperfusion injury is a symptom of diabetes (See Tabatabaie et al. Medline Abstract, AN 97309474, 1997). A method known to be useful for treating the underlying etiology, would inherently be useful for treating the symptom caused by the etiology. Further, since the tea

Art Unit: 1617

disclosed by Ning and Wang are known to be effective for treating ischemia or diabetes, the amounts of lignin glycoside therein would be reasonably be considered therapeutically effective. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Regarding the effective amounts herein, note the effective amount of hydrolysable tannins or lignin glucoside is 0.1 to 100 mg/kg of body weight a day. See page 40, lines 12-15 in the specification.

Claim Rejections 35 U.S.C – 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (CH 1077644A, Abstract, DERWENT ACC-NO: 1997-065937, of record, and English translation provided by applicants), Ning (CH 1113711, Abstract from DERWENT-ACC-NO: 1997-416112, of record and the English Translation provided by Applicants) and Tanuma (AB and AC), and in further view of Kim et al. (BIOSIS Abstract, AN 1988:268183) and Wen et al .

8. Wang teaches method of treatment of diabetes comprising administering ginseng in the form of tea to the patient. See the abstract. A tea bag containing 1.8 gram of ginseng powders and extract. See page 3, the application example of the English translation. Ning teaches method of treatment of ischemia comprising administering ginseng in the form of tea to the patient. See the

Art Unit: 1617

abstract. A tea bag weigh about 15 g, which contains about 1% of ginseng extract. See, page 2, the last paragraph bridging to page 3, the third paragraph of the English translation. The ginseng is administered in the form of tea. See both abstracts. The primary references do not teach expressly the employment of lignin glycoside for treatment of diabetes.

9. However, Tanuma teach that the particular PARG inhibitor herein, lignin glycoside, is found in ginseng. See the above discussion. Tanuma further teach that the lignin glycoside is hot water extractable. See page 6 in JP 3-205402 the translated copy. Therefore, it is prima facie obvious to use the hot water extractable part for treatment of diabetes. Regarding the functional limitation about the detailed enzyme function, i.e., inhibitor of poly(ADP-ribose) glycohydase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Claim 49 is properly rejected because it is well known in the art that reperfusion injury is a symptom of diabetes. A method known to be useful for treating the under lying etiology, would have been reasonably expected to be useful for treating the symptom caused by the etiology. Further, since the tea disclosed by Ning and Wang are known to be effective for treating ischemia or diabetes, the amounts of lignin glycoside therein would be reasonably be considered therapeutically effective. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for the claimed substance is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. The employment of Ginseng for

Art Unit: 1617

treating Ischemia or reperfusion injury would also obvious in view of Kim et al. and Wen et al. Both Kim et al. and Wen et al. teaches that ginseng extract are useful for treating ischemia and/or perfusion injury. See, the abstract in Kim and the abstract in Wen et al.

Response to the Arguments

Applicants' arguments presented in the appeal briefing have been fully considered, but are not persuasive for reasons discussed below.

The claimed method read on administering a composition comprising lignin glucoside to a subject who have ischemia or reperfusion injury.

The argument that isolation of lignin glucoside requires more than hot water extract is not the issue since the claim read on administering a composition comprising lignin glucoside. The hot water extract comprising lignin glucoside (with other ingredient).

The assertion that Wang does not teach treatment of diabetes is in error. Wang expressly states "It (the ginseng tea) is particularly suitable for diabetes patients, with therapeutic and preventing effects," See the abstract in the English translation. Similarly, Ning expressly teaches the tea bag is for person experiencing Myocardial ischemia. See the abstract in the English translation.

The examiner agree that prior art does not teach expressly that lignin glucoside is the active ingredients for treating ischemia or reperfusion injury. However, the claimed method, i.e., administering composition comprising lignin glucoside to a subject who experiencing ischemia or reperfusion injury, has been clearly anticipated by Wang and Ning, as discussed above.

Even assuming Wang and Ning merely teach generally the usefulness of the ginseng tea for various condition, administering the ginseng tea to person experiencing ischemia or diabetes

Art Unit: 1617

would be prima facie obvious to one of ordinary skill in the art since the tea are known to be beneficial to person experiencing ischemia or diabetes. It would be further obvious in view of Kim et al. and Wen et al. since these reference teach expressly the usefulness of ginseng for treating ischemia and/or reperfusion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

August 3, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200